PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference T035P03-WO	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/TR 03/00082	International filing date (day/month/year) 26.09.2003	Priority date (day/month/year) 26.09.2002

International Patent Classification (IPC) or both national classification and IPC
C12Q1/68

Applicant
KÖKSALAN, Orhan, Kaya et al.

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
26.04.2004	03.03.2005

Name and mailing address of the international preliminary examining authority:
European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer
Brochado Garganta, M .
Telephone No. +49 89 2399-8935

Form PCT/IPEA/409 (Cover Sheet) (January 2004)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/TR 03/00082

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-7 as originally filed

Claims, Numbers

1-2 received on 02.10.2004 with letter of 27.09.2004

Drawings, Sheets

1/2-2/2 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☒ furnished subsequently to this Authority in written form.

   ☒ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/TR 03/00082

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-2
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-2
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-2
	No:	Claims	

2. Citations and explanations

see separate sheet

INTERNATIONAL PRELIMINARY EXAMINATION REPORT - SEPARATE SHEET

International application No. PCT/TR 03/00082

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following document:

   D1: FRANCESCA BRUNELLO ET AL.: "IDENTIFICATION OF 54 MYCOBACTERIAL SPECIES BY PCR-RESTRICTION FRAGMENT LENGTH POLYMORPHISM ANALYSIS OF THE HSP65 GENE" JOURNAL OF CLINICAL MICROBIOLOGY, vol. 39, no. 8, 2001, pages 2799-2806, XP002286615

2. The amendments filed on 02.10.04 do not introduce additional subject-matter, which extends beyond the content of the application as filed. Therefore, the amendments meet the requirements of Article 34(2)(b) PCT.

   Claims 1 and 2 as filed on 0.2.10.04 correspond to claims 1 and 8 of the original set of claims.

3. Novelty (Article 33(2) PCT) and inventive step (Article 33(3) PCT)

   The document D1 is regarded as being the closest prior art to the subject-matter of claims 1 and 2, relating to a DNA molecular size marker, and discloses the identification of 54 mycobacterial species by PCR-restriction fragment length polymorphism analysis of the *hsp65* gene, wherein molecular size markers are used for the analysis (see pages 2799-2805 and tables 2 and 3).

   The subject-matter of claims 1 and 2 differs from the disclosure in D1 in that the fragments have different sizes.

   The subject-matter of claims 1 and 2 is therefore new (Article 33(2) PCT).

   The problem to be solved by the present invention may be regarded as to provide an improved DNA molecular size marker, suitable for analysis of mycobacteriae.

The molecular size markers of the present application contain fragments of exactly the same size as the restriction fragment of mycobacteriae. These markers are specific and allow a rapid and accurate determination of the tested strains.

The restriction analysis of mycobacteriae is usually done by using commercially available molecular size markers not really specific for mycobacteriae, which is also the case in D1. No reference is given for the need of other molecular size markers.

Thus, claims 1 and 2 of the present application are considered to involve an inventive step (Article 33(3) PCT).